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EXAMINER

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ART UNIT

PAPER NUMBER

1656

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/937,779	DAHLQVIST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lindsay Odell	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-45, 47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>28 September 2001</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Application Status*

1. In response to the previous Office action, a written restriction requirement (mailed on September 15, 2004), Applicants filed a response received on April 21, 2005. Claims 46 and 48 are pending in this instant Office action.

### *Election*

2. Applicant's election with traverse of Group D, Claims 46 and 48, drawn to processes for producing triacylglycerol using nucleotide sequences related to SEQ ID NO: 1 or encoding SEQ ID NO: 2, in the reply filed on April 21, 2005 is acknowledged. The traversal is on the grounds(s) that the PDAT enzymes of the present invention are characterized through an amino acid conserved consensus sequence, and, hence, all sequences should be examined together. This is not found persuasive because Applicants have not addressed the reasons previously cited by the Examiner for why the Groups of claims lack the same or corresponding special technical feature. In particular, the traversal does not address why claims drawn to nucleic acids having a particular nucleic acid sequence or encoding a particular amino acid sequence should be examined with polypeptides having particular amino acid sequences. The Examiner acknowledges Applicant's reminder that the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.414 *et seq.* and permit a reasonable number of nucleotide sequences to be claimed in a single application. The Examiner maintains that a single nucleotide sequence constitutes a reasonable number in this case since the nucleotide sequences of the

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instant application are structurally distinct and do not share the same or a corresponding technical feature. Thus, the Examiner maintains that the Groups of claims do not relate to a single general inventive concept under PCT Rule 13.1 for the previously cited reasons.

The requirement is still deemed proper, and is, therefore, made FINAL. Claims 28-49 are pending in the instant Office action. Claims 28-45, 47 and 49 are withdrawn as non-elected inventions. Claims 46 and 48, to the extent that they read on the elected subject matter, are examined herein.

### ***Priority***

3. The instant application is granted the benefit of priority for the U.S. provisional Application No. 60/180687 filed on February 7, 2000 as requested in the declaration.

4. The instant application is granted the benefit of priority for the foreign application 99106656.4 filed in the European Patent Office on April 1, 1999 and foreign application 99111321.8 filed in the European Patent Office on June 10, 1999 as requested in the declaration. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d) or (f), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

5. The information disclosure statement (IDS) filed September 28, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion

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which caused it to be listed. The following references were not considered for the reasons described below:

a) A copy of the documents Lyne *et al.* and Nelson *et al.* have not been received by the Office. Copies of the EMBL sequences associated with these references have been received by the Office; however, sequences should not be referenced by a document with which they are associated, but by their EMBL accession information only.

All other documents in said Information Disclosure Statement were considered as noted by the examiner's initials in the attached copy.

#### ***Compliance with Sequence Rules***

6. The sequence listing, filed in computer readable form (CRF) and paper copy on July 2, 2002, has been received and entered. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

a) On page 3, line 31, the sequence of a conserved sequence string of a lipase motif is disclosed without SEQ ID NO identification.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or

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1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO. Appropriate correction is required.

### ***Objections to the Specification***

7. The specification is objected to because the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: ---Processes for producing triacylglycerol using genes that encode phospholipid:diacylglycerol acyltransferases ---.

8. The abstract of the disclosure is objected for not completely describing the disclosed subject matter (MPEP § 608.01(b)) and for minor informalities. The word "catalysing" is misspelled, and should be spelled ---catalyzing---. The phrase "to **the said** enzymes" (emphasis added) contains two articles. Furthermore, the abstract should not contain legal terminology (i.e., "said"). In addition, it is noted that in many databases and in foreign countries the Abstract is crucial in defining the disclosed subject matter; thus, its completeness is essential. The Examiner suggests the inclusion of the enzyme name phospholipid:diacylglycerol acyltransferase (as disclosed on page 1), the source species of the phospholipid:diacylglycerol acyltransferase, *Saccharomyces cerevisiae*, and the disclosed method steps for producing triacylglycerols, for completeness. The Examiner suggests following language for the Abstract:

---The present invention relates to the isolation, identification and characterization of nucleotide sequences encoding enzymes catalyzing the transfer of fatty acids from phospholipids to diacylglycerol (phospholipid:diacylglycerol acyltransferases, particularly from *Saccharomyces cerevisiae*), to phospholipid:diacylglycerol

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acyltransferases and to processes for the production of triacylglycerols using yeast and plants expressing nucleotides that encode phospholipid:diacylglycerol acyltransferases---

Appropriate correction is required.

9. The specification is objected to for being improperly arranged. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino

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acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Appropriate correction is required.

10. The specification is objected to because the first paragraph does not contain a claim for priority from U.S. Provisional Application Number 60/180,687. The Application data, including application status must be cited in the first paragraph of the specification (see 37 CFR 1.78(a) and MPEP § 201.11). Appropriate correction is required.

11. The specification is objected to for the improper use of trademarks. The use of the trademark "pBLUESCRIPT" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Please see pages 12 and 20 of the specification for instances of improper trademark use. Correction is required.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

### *Claims Objections*

12. Claim 46 is objected to because of the following informalities: the phrase "whereby **the said** nucleotide sequence" (emphasis added) contains two articles. The Examiner suggests deleting the article "the" from this phrase. Appropriate correction is required.

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13. Claim 46 is objected to because it depends on a claim to a non-elected claim (claim 40).

In the instant application, Applicant's have elected to prosecute process claims 46 and 48, relating to SEQ ID NO 1. Claim 46 depends on claim 40, which contains product claims related to SEQ ID NO's 1, 3, 4, 5, 7, 9, 10, 11, 12, 19, 21, 23, 24, 25, 26, 28, 29, 30, 31. The instant claim will be examined in as much as they are related to SEQ ID NO: 1. Claim 46 will be examined with claim 40 language included as follows:

---46. A process for the production of triacylglycerol, comprising growing a transgenic cell or organism comprising one or more of the following:

- a) a nucleotide sequence a<sub>1</sub>) to a<sub>4</sub>),
- b) a gene construct b<sub>1</sub>), and
- c) a vector c<sub>1</sub>),

wherein

- a<sub>1</sub>) is a nucleotide sequence as set forth in SEQ ID NO. 1 or a homologous nucleotide sequence which is at least about 40% identical to a nucleotide sequence of SEQ ID NO. 1.
- a<sub>2</sub>) is a nucleotide sequence, a portion, derivate, allele or homolog thereof selected from the group consisting of sequences as set forth in SEQ ID NO. 1 . . . ., or a functional fragment, derivate, allele, homolog or isoenzyme of the enzyme encoding amino acid sequence,
- a<sub>3</sub>) is a partial nucleotide sequence which corresponds a full length nucleotide sequence selected from the group . . . .
- a<sub>4</sub>) is a nucleotide sequence which is at least 40% identical to a nucleotide sequence selected from the group consisting of those sequences set forth in SEQ ID NO. 1 . . . .
- b<sub>1</sub>) is a gene construct comprising a nucleotide sequence a ), operably linked to a heterologous nucleic acid, and
- c<sub>1</sub>) is vector comprising a gene construct b<sub>1</sub>), or a nucleotide sequence a<sub>1</sub>)

under conditions whereby said nucleotide sequence

- a<sub>1</sub>) is a nucleotide sequence as set forth in SEQ ID NO. 1 or a homologous nucleotide sequence which is at least about 40% identical to a nucleotide sequence of SEQ ID NO. 1,
- a<sub>2</sub>) is a nucleotide sequence, a portion, derivate, allele or homolog thereof selected from the group consisting of sequences as set forth in SEQ ID NO. 1 . . . ., or a functional fragment, derivate, allele, homolog or isoenzyme of the enzyme encoding amino acid sequence,

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- a<sub>3</sub>) is a partial nucleotide sequence which corresponds to a full length nucleotide sequence selected from the group consisting of sequences . . . . ,
  - a<sub>4</sub>) is a nucleotide sequence which is at least 40% identical to a nucleotide sequence selected from the group consisting of those sequences set forth in SEQ ID NO. 1 . . . . ,
- is expressed.---

Appropriate correction to the elected claim is required. The Examiner notes that the language above is not suggested claim language, but the Examiner's interpretation of the confusing language of record.

14. Claim 46 is objected to because of the following informalities:

- a) sections a<sub>1</sub>, a<sub>2</sub>, a<sub>3</sub> and a<sub>4</sub> as set forth in both the first part of the claim and the second part of the claim (see claim interpretation above) are redundant
- b) the use of the lettering a<sub>1</sub>, a<sub>2</sub>, a<sub>3</sub> and a<sub>4</sub> is awkward. Examiner suggests using the letters i, ii, iii . . . etc., which are subgroups of group a)

Appropriate correction is required.

15. Claim 48 is objected to because of the following informalities: the use of the lettering a<sub>1</sub>, a<sub>2</sub>, a<sub>3</sub> and a<sub>4</sub> is awkward. The Examiner suggests using the letters a), b), c) . . . etc. to list the nucleotide sequences. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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16. Claims 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. The phrase "a ) a nucleotide sequence  $a_1$ ) to  $a_4$ )" (see claim interpretation above) is confusing because the conjunction of sequences  $a_1$ ) to  $a_4$ ) is unclear. Does Applicant mean to claim nucleotide sequences  $a_1$  and  $a_2$  and  $a_3$  and  $a_4$ , or a nucleotide sequences  $a_1$  or  $a_2$  or  $a_3$  or  $a_4$  ? Clarification is required.

17. Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. The word "about" in the phrase "at least **about**" (emphasis added) in part  $a_1$ ) of the claims is a relative term that renders the claims indefinite. The word "about" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, is a sequence identity of at least 36% or at least 39.8% encompassed by the scope of the claims? Clarification is required.

18. Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a nucleotide sequence, a portion, derivate, allele or homolog thereof selected from the group consisting of sequences as set forth in SEQ ID NO. 1 . . ." as it appears in part  $a_2$ ) of claims 46 and 48 is confusing because the meaning of the words "portion, derivate, allele and homolog" describe molecules that are related, but not identical, to

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SEQ ID NO: 1. However, the aforementioned phrase reads on exactly SEQ ID NO: 1. Does Applicant mean to claim exactly SEQ ID NO: 1, as the phrase is worded, or does Applicant mean to claim a portion, derivate, allele or homolog of SEQ ID NO: 1? Clarification is required.

19. Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a functional fragment, derivate, allele, homolog or isoenzyme of the enzyme encoding amino acid sequence" is confusing. To begin, the aforementioned phrase is an elaboration of a nucleotide sequence: the words "isoenzyme" and "enzyme" in the phrase do not describe nucleic acid molecules, but polypeptides. In addition, enzymes do not function to encode amino acid sequences, but are described by amino acid sequences. Furthermore, it is unclear what "amino acid sequence" is the amino acid sequence that Applicant's intend to claim. Does Applicant mean to claim a nucleic acid that encodes a functional fragment, derivate, homolog or isoenzyme of the enzyme encoded by SEQ ID NO: 1? Or does Applicant mean to claim a nucleic that is a fragment, derivate, allele or homolog of the nucleic acid that encodes a particular amino acid sequence?

The terms "derivate, allele, homolog and isoenzyme" as used in the aforementioned phrase are additionally unclear as to the metes and bounds they impart on the claimed subject matter. An explicit definition for each of the terms is not disclosed in the specification. In addition, the terms are not clearly defined in the art with a single meaning. It is not clear whether the terms, as used in the claims, refer to structural or functional variants, nor is it clear

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what level of similarity must exist for a molecule to be considered a derivate, allele, homolog or isoenzyme. Clarification of all of the above points is required.

20. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 provides for the use of particular nucleotide sequences for the production of triacylglycerol, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 48 is further rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 46 and 48 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject

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matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to methods for producing triacylglycerol by growing cells wherein nucleotides related to SEQ ID NO: 1 are expressed (claim 46) or by using nucleotides related to SEQ ID NO: 1 (claim 48); said claims lack adequate written description for genus of nucleotides related SEQ ID NO: 1.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (see *Enzo Biochemical*, 63 USPQ2D 1609, CAFC 2002).

*University of Rochester v. G.D. Searle & Co.* (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v.*

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*G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from Enzo Biochemical (see above).

On pages 20 and 28-29 of the instant specification, nucleotide sequences from five species for genes encoding phospholipid:diacylglycerol acyltransferase (PDAT) are disclosed, including the PDAT gene from *Saccharomyces cerevisiae* which has a structure described by SEQ ID NO: 1. Applicants have described structural features of the genus relating to SEQ ID NO: 1; however, a functional limitation for the genus of genes that are at least 40% identical to SEQ ID NO: 1 is lacking. In part a<sub>2</sub>) of the instant claims, the word "functional" preceding the terms "fragment, derivate, allele, homolog or isoenzyme" does not impart a real limitation, since the function can be any function, and not necessarily that of a PDAT. In addition, the common structural characteristics of the species in the instant genus that correlate to a functional limitation are lacking. In view of the prior art, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, claims drawn to the instant genus of polypeptides are not adequately described.

22. Claims 46 and 48 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for growing yeast and *Arabidopsis thaliana* in which a gene described by SEQ ID NO: 1 is expressed, does not reasonably provide enablement for the genus of processes wherein any transgenic cell or organism is grown in which any homolog of SEQ ID NO. 1 is expressed (claim 46) or any use of any homolog of SEQ ID NO: 1

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for producing triacylglycerol (claim 48). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to use the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The specification contains one working example of a transgenic cell and one example of a transgenic organism that can be used to make triacylglycerol: yeast that express SEQ ID NO: 1 and *Arabidopsis thaliana* that express SEQ ID NO: 1. Applicants, however, present no guidance

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or working examples of the use of the genus of transgenic cells and transgenic organisms or the genus of nucleotides included in the scope of the claims. The nature of the invention is such that SEQ ID NO: 1 encodes a functional protein, a phospholipid:diacylglycerol acyltransferase (PDAT), which catalyzes the transfer of phospholipids to diacylglycerol; and with a deviation from the known sequence, the predictability of functionality becomes extremely low. The predictability of making isolated nucleotides that encode polypeptides as little as 40% sequence identity to SEQ ID NO: 1 which also maintain the function of PDAT can be increased by comparing the sequences of a genus of known PDAT's to SEQ ID NO:1 and identifying important/conserved residues; however, the specification discloses only a few examples nucleotides that encode PDAT's. The state of the prior art is such that a comparison of a sufficient number of sequences of PDAT's to the disclosed PDAT from *Saccharomyces cerevisiae* cannot be performed. In addition, the nature of transgenic organisms is that they are unstable and difficult to make; to make all of the transgenic organisms that express molecules related to SEQ ID NO: 1 included in the scope of the claims is wholly unpredictable. The breadth of the claims and the unpredictability of the art render the instant claims not enabled to the full extent of their scope without undue experimentation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 46 and 48 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/55631 (Lardizabal *et al.*, see IDS). The instant claims are drawn to methods of producing triacylglycerol (triglyceride) by growing transgenic host cells expressing a nucleotide sequence that is homologous to SEQ ID NO: 1 (see 112, 2nd paragraph rejection of part a<sub>2</sub>).

Lardizabal *et al.* teach transgenic host cells that express nucleic acids encoding diacylglycerol acyltransferases (DAGAT) to modify triacylglycerol levels (see page abstract and page 61). Expressing DAGAT inherently increases triacylglycerol production because DAGAT catalyzes the formation of triacylglycerol from fatty acyl-CoA and diacylglycerol substrates. In the broadest reasonable interpretation of the claims, DAGAT is a homolog of PDAT because, like PDAT, it is a diacylglycerol acyltransferase (see page 637, column 1). Thus, Lardizabal *et al.* anticipate claims 46 and 48.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson *et al.* (see PTO-892) in further in view of Genbank Accession Entry X77395 (see PTO-892).

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The instant claims are drawn to methods of producing triacylglycerol (triglyceride) by growing transgenic host cells expressing a nucleotide sequence that are homologous to SEQ ID NO: 1 (see 112, 2nd paragraph rejection of part a<sub>2</sub>).

Genbank Accession Entry X77395 teaches the open reading frame that encodes *S. cerevisiae* phospholipid:diacylglycerol acyltransferase (PDAT) (identified as N2042). This reference does not teach the DNA molecule in vectors with selectable markers, host cells, or in a process for producing transgenic cells.

Watson *et al.* teach the usefulness of investigating encoded proteins from their respective genes using vectors with selectable markers, host cells, and transformations into plant cells of plants (see pages 99, 119-23, 235-9, 273-4 and 281-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the DNA disclosed in the above reference in vectors with selectable markers, host cells, and processes for producing transgenic cells because the references specifically disclose open reading frames of genes which encode proteins. The motivation for such experiments is found in the Preface of Watson *et al.*, which states that "the great power of recombinant DNA techniques comes from the ability to explore gene function by manipulation of genes and then introducing them back into cells" to bring "about our understanding of living organisms." The Examiner suggests adding the step of isolating triacylglycerol to the methods of claims 46 and 48 to overcome the rejection.

#### ***Other Art for Comment/Examiner's Suggestions***

The following are cited to complete the record:

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- a) Genbank Database entry AI398644, February 1999 (see attached) teaches the open reading frame that encodes *Neurospora crassa* acyltransferase, which is a homolog to SEQ ID NO: 1. The nucleotide was isolated earlier by Nelson *et al.* (see PTO-892) as evidenced by Genbank Database Entry AI398644; however, Nelson *et al.* do not identify the open reading frame that encodes the acyltransferase for expression in a host cell.
- b) Genbank Database entry AL 035263 teaches the open reading from that encodes *S. pombe* phospholipid:diacylglycerol acyltransferase (pages 11 and 23-24).

### ***Conclusion***

25. Claims 46 and 48 are rejected for the reasons identified in the numbered sections of the Office action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.  
June 22, 2005

  
**KATHLEEN KERR, PH.D.**  
**PRIMARY EXAMINER**